

Kaczmarek, Chris

From: Taub, Cynthia <CTaub@steptoe.com>
Sent: Thursday, May 22, 2014 9:53 AM
To: 'Talbert, Stephanie (ENRD)'
Cc: Allison_Starmann@americanchemistry.com; Goldberg, Seth; Kaczmarek, Chris; Ross, Philip
Subject: RE: Next meeting date

Yes, 2pm on the 28th at DOJ works.

Thanks,

Cynthia

Cynthia L. Taub
ctaub@steptoe.com

Step toe

+1 202 429 8133 direct Steptoe & Johnson LLP
+1 202 261 0512 fax 1330 Connecticut Avenue, NW
Washington, DC 20036
www.steptoe.com

This message and any attached documents contain information from the law firm Steptoe & Johnson LLP that may be confidential and/or privileged. If you are not the intended recipient, please do not read, copy, distribute, or use this information. If you have received this transmission in error, please notify the sender immediately by reply e-mail and then delete this message.

Nonresponsive



From: Taub, Cynthia [<mailto:CTaub@steptoe.com>]
Sent: Wednesday, May 21, 2014 9:47 AM
To: Talbert, Stephanie (ENRD)
Cc: Allison_Starmann@americanchemistry.com; Goldberg, Seth; Kaczmarek, Chris; Ross, Philip
Subject: RE: Next meeting date

Stephanie-

Thank you for this information.

With regard to the next meeting date, May 28th works for Seth and I. Allison will not be available either day next week, so we will carry on without her. How about 9-11 am or 1-3 pm? We would be happy to host the meeting at Steptoe if that works for you.

With regard to the implementation letter, what we meant by "follow-on" was provided in our term sheet as follows:

"EPA should commit to providing clear guidance as to how it will apply the new data requirements to new active ingredients, new formulated products for existing actives where the new regulation creates data gaps for the active, ***active ingredient applications for substances that already are registered (follow on active applications)***, and me-too formulated products. The guidance also should explain the timing and process through which EPA plans to impose these new requirements on existing registrations. Among the issues that should be answered by such guidance are: will EPA hold up amendments and/or other actions until new data are submitted, will EPA issue data call-ins for the new data and, if so, on what schedule, will EPA plan to impose the new requirements through registration review?" (emphasis added).

Please us know whether all of the above will be addressed in the implementation letter.

In follow up to our last meeting, attached please find a sample EPA-approved label that includes the word "fungicide" and is not for use against public health organisms. We removed the company name, product name, active ingredient, establishment number, and use rate information from the attached copy. This is just one example of many labels available on NPIRS that include "fungicide" claims on the label where the fungicide claim is not based on activity against fungi pathogenic to man or other animals.

Finally, at the last meeting, we discussed the two "principles" ACC listed in the term sheet for the USI (principles for when tolerances and non-dietary oral risk assessments would be required). We understand EPA's position is that both of these subjects are outside 158W and therefore are not within the scope of potential settlement. ACC is willing to remove these two "principles" from its list of terms, and therefore remove these issues from the settlement discussions, as long as EPA's attorneys confirm in writing, to both ACC and AD, that ACC and its members will be immediately free to discuss these two topics with AD directly. Confirmation by email will suffice.

We look forward to your response.

Cynthia

Cynthia L. Taub
ctaub@steptoe.com

Steptoe

+1 202 429 8133 direct
+1 202 261 0512 fax

Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036
www.steptoe.com

This message and any attached documents contain information from the law firm Steptoe & Johnson LLP that may be confidential and/or privileged. If you are not the intended recipient, please do not read, copy, distribute, or use this information. If you have received this transmission in error, please notify the sender immediately by reply e-mail and then delete this message.

Nonresponsive [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]